

## REMARKS

An Office Action was mailed in the above-captioned application on March 15, 2007. In such Office Action claims 39-80 were pending. Claims 39-80 were rejected. Claims 39, 40, 42, 44, 52, 54, 56, 58, 60, 62, 64, 67 and 73 were objected to. Applicants request reconsideration of the application, withdrawal of all rejections, and allowance of the application in view of the amendments and remarks below.

### The Amendments to the Specification

The specification has been amended at paragraph [0059] to note that “[i]n some variations, the respiratory drug condensation aerosol has a MMAD of less than 5 microns.” As acknowledged in the Office Action, this limitation is disclosed in U.S. Provisional patent application Serial No. 60/429,364 (e.g., at page 3, lines 7-8) which the present application incorporated by reference in its entirety. No new matter is introduced by these amendments to the specification. The Examiner is respectfully requested to enter the amendments to the specification.

### The Amendments to the Claims

Without prejudice to the Applicants’ rights to present claims of equal scope in a timely filed continuing application, in order to expedite prosecution and issuance of the application, the Applicants have amended claims 39 and 67 to include the Markush group (except for “caffeine”) of claims 40 and 73, respectively. Applicants also have amended claims 43, 59, 77 and 80 to correct dependency. Applicants have also cancelled claims 40, 42, 44, 52, 54, 56, 58, 60, 62, 64 and 73 and added new claims 81-95.

The addition of new claims does not introduce new matter. Support for new claims 81-95 is found throughout the specification and in the original claims. Support for the rate of condensation aerosol formation is found, e.g., at paragraph [0060]. Applicants respectfully submit that the amendments to the claims put the case in condition for allowance. The Examiner is respectfully requested to enter and allow all claims.

### **Claim Objections**

The Examiner rejected claims 40, 42, 44, 52, 54, 56, 58 60, 62, 64 and 73 as missing the term “and” or “or” before the last species in the recited Markush groups. As noted above, Applicants have cancelled these claims.

The Examiner objected to claims 39 and 67 because they recite the limitation “less than 5 microns” which is not disclosed in the specification. As noted above, Applicants have amended the specification as suggested by the Examiner.

Applicants believe that this addresses the Examiner’s concerns and respectfully request reconsideration of the claim objections on this basis.

### **Double Patenting Rejections**

Claims 39-80 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 6,716,415; 6,716,416; 6,716,417; 6,737,042; 6,737,043; 6,740,307; 6,740,308; 6,740,309; 6,743,415; 6,759,029; 6,776,978; 6,780,399; 6,780,400; 6,783,753; 6,797,259; 6,803,031; 6,805,853; 6,805,854; 6,814,955; 6,855,310; 7,052,680; 7,052,679; 7,048,909; 7,045,119; 7,045,118; 7,035,575; 7,029,658; 7,022,312; 7,018,621 and 7,018,620.

Also, claims 39-80 were provisionally rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application Nos. (Publication document Nos.) 2003138382; 20030206869; 20040009128; 20040096402; 20040099266; 2004099269; 20040101481; 20040105818; 20040105819; 20040126326; 20040126327; 20040126328; 20040126329; 20040127481; 20040127490; 20040156788; 20040156789; 20040156790; 20040156791; 2004161385; 20040167228; 20040170569; 20040170570; 20040170571; 20040170572; 20040170573; 20040171609; 20040184996; 20040184997; 20040184998; 20040184999; 20040185000; 20040185001; 20040185002; 20040185003; 20040185004; 20040185005; 20040185006; 20040185007; 20040185008; 20040186130; 20040191179; 20040191180; 20040191181; 20040191182; 20040191183; 20040191184; 20040191185; 20040202617 and 20040228807 and Application Nos. 10/749,537; 10/749,539; 10/718,982; 10/749,783; 10/768,205; 10/146,516; 10/912,462; 10/146,516; 10/150,056; 10/150,267; 10/150,268; 10/150,591; 10/150,857; 10/151,596; 10/151,626; 10/152,639; 10/152,640; 10/152,652; 10/153,139; 10/153,311; 10/153,313;

10/153,831; 10/153,839; 10/154,594; 10/154,765; 10/155,097; 10/155,373; 10/155,621; 10/155,703; 10/155,705; 10/280,315; 10/302,010; 10/302,614; and 10/322,227. *Id.* at 8-9.

With respect to the foregoing rejections, the Examiner states: “Here claims 39-80 are generic to all that is recited in claims of [the listed U.S. Patents and copending Applications]. That is, claims of [the listed U.S. Patents and copending Applications] fall entirely within the scope of claims 39-80, or in other words, claims 39-80 are anticipated by claims of [the listed U.S. Patents and copending Applications]. Specifically, the compositions for delivery and the kits comprising the compositions and devices for their delivery of the instant claims are the same as compositions and kits of [the listed U.S. Patents and copending Applications]. The instant claims recite all the therapeutic agents included in the [the listed U.S. Patents and copending Applications].” Office Action at 3-5.

Applicants file herewith terminal disclaimers with respect to U.S. Patent Nos. 7,090,830 and 6,682,716 as well as U.S. patent application Serial Nos. 10/696,959 and 11/504,419. As to the remaining U.S. Patents and copending Applications listed by the Examiner, Applicants submit that the present claims, as amended, are not generic to all that is recited in the claims of those U.S. Patents and copending Applications. Furthermore, Applicants submit that therapeutic agents recited in the present claims, as amended, are not recited in the claims of those U.S. Patents and copending Applications.

Applicants believe that this addresses the Examiner’s concerns and respectfully request reconsideration of the application, withdrawal of all rejections, and allowance of the application in view of these actions and remarks.

### **Closing Remarks**

The Applicants appreciate the Examiner’s careful and thorough review of the application and submit that the Examiner’s concerns have been addressed by the amendments and remarks above. The Applicants accordingly request the Examiner to withdraw all rejections and allow the application. In the event the Examiner believes a

telephonic discussion would expedite allowance or help to resolve outstanding issues, or prosecution of the application, then the Examiner is invited to call the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

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/Katherine Lobel-Rice/

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